



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/650,509 | 08/27/2003 | Jeffrey Hubbell | CIT 2606 CIP CON | 7219 |
| 23579 | 7590 | 01/07/2010 | EXAMINER | |
| Pabst Patent Group LLP | | | LANKFORD JR, LEON B | |
| 1545 PEACHTREE STREET NE | | | | |
| SUITE 320 | | | ART UNIT | PAPER NUMBER |
| ATLANTA, GA 30309 | | | 1651 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 01/07/2010 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/650,509
Filing Date: August 27, 2003
Appellant(s): HUBBELL ET AL.

Rivka Monheit
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the reply brief filed 12/08//08 .

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct. The rejection over 6894022 was previously dropped and was incorrectly included in the Examiner's Answer.

For further clarification:

On 3/21/2006, the examiner required an election of species. In response, on 5/10/2006, applicants elected the Factor XIIIa substrate domain of SEQ ID No. 15 for the transglutaminase substrate domain, parathyroid hormone (PTH) for the domain

containing a bioactive factor and fibrin for the matrix, with traverse. On 8/26/2006, the examiner indicated that the elected species was free of the art (no claim contains the elected species) and pursuant to 37 CFR 1.146 the examiner rejected the generic claim 1 (and the other claims as they read on the generic). On 10/05/2007, the generic claim was finally rejected on the grounds of obviousness-type double patenting.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| | | |
|-----------|---------------|---------|
| 6331422 | Hubbel et al | 4-1998 |
| 6607740 | Hubbel et al | 10-2000 |
| 7247609 | Lutolf et al | 12-2002 |
| 10/323046 | Hubbell et al | 12-2002 |

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5, 7, 9-14, 16-22, 26-30, 34 and 35 stand finally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6331422. Although the conflicting claims are not identical, they

are not patentably distinct from each other. The generic claims are encompassed by the patented claims thus rendering the instant claims obvious.

Claims 1-5, 7, 9-14, 16-22, 26-30, 34 and 35 stand finally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6607740. Although the conflicting claims are not identical, they are not patentably distinct from each other. The generic claims are encompassed by the patented claims thus rendering the instant claims obvious.

Claims 1-5, 7, 9-14, 16-22, 26-30, 34 and 35 stand finally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-20 of U.S. Patent No. 7247609. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The generic claim 1 requires a composition comprising a matrix and a bidomain protein or peptide having an amino acid sequence that comprises a transglutaminase substrate domain and a polypeptide growth factor, wherein the protein or peptide is covalently bound to the matrix by the transglutaminase substrate domain. Claims 14-20 of the patent are a species of the instantly claimed invention and as such are encompassed by the claimed invention and thus anticipate the claimed invention and thus rejection on the grounds of nonstatutory obviousness-type double patenting is required.

The generic claims are encompassed by the patented claims thus rendering the instant claims obvious.

Claims 1-5, 7, 9-14, 16-22, 26-30, 34 and 35 stand finally provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-6, 9, 13, 14, 16-19 & 22-46 of copending Application No. 10/323046. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The generic claim 1 requires a composition comprising a matrix and a bidomain protein or peptide having an amino acid sequence that comprises a transglutaminase substrate domain and a polypeptide growth factor, wherein the protein or peptide is covalently bound to the matrix by the transglutaminase substrate domain. The claims of the patent application are a species of the instantly claimed invention and as such are encompassed by the claimed invention and thus anticipate the claimed invention and thus rejection on the grounds of nonstatutory obviousness-type double patenting is required.

The generic claims are encompassed by the application's claims thus rendering the instant claims obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

(10) Response to Argument

Applicant argues that the patent rules require common ownership for a double patenting rejection to be made. However, it is respectfully submitted that that is not a requirement.

Regarding applicant's argument that double patenting rejections require common ownership:

A double patenting issue may arise between two or more pending applications, or between one or more pending applications and a patent. It is respectfully submitted that applicant has too narrowly read section M.P.E .P. § 804II(B). A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). The conditions discussed by applicant are a particular situation where an ODP rejection applies and a situation wherein the ODP can be obviated by a terminal disclaimer. The limitations discussed by applicant are not meant to limit the scope of the ODP rejection, i.e., common ownership is not necessary for an ODP to be made.

Regarding the ODP rejection over 7247609:

Applicant's arguments directly to specific claim species (besides that species elected) are moot as the rejection is based on the generic claim 1 and the other claims only as they read on the generic.

Applicant's arguments are persuasive as to claims 1-13 of the '609 patent however claims 14-20 clearly anticipate the instant generic claims and as such a rejection under obviousness-type Double Patenting is required. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Applicant argues that the claims of the present invention do not require an enzymatic degradation site between the two domains of the bidomain peptide, however applicant ignores the fact that the present claims are constructed with the transition phrase "comprising" and thus permit the inclusion of other components.

Regarding the provisional ODP rejection over 10/323046:

Applicant argues that the claims of the present invention do not require an enzymatic degradation site between the two domains of the bidomain peptide, however applicant ignores the fact that the present claims are constructed with the transition phrase "comprising" and thus permit the inclusion of other components.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Conferees:

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Michael G. Wityshyn/
Supervisory Patent Examiner
Art Unit 1651